Registration No 7946-33



Jamiary 31, 2012

Ms. Shaja Joyner
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Mycoject Ultra Hp (EPA Reg. No. 7946-33)

- Final printed label

Dear Ms. Joyner:

On behalf of J.J. Mauget Co., SciReg, Inc. is submitting one copy of the final printed label for Mycoject Ultra Hp (EPA Reg. No. 7946-33), as required by the Agency's December 20, 2011 letter.

Should you have any questions, please let me know.

Sincerely,

Frederick T. Smith

Senior Regulatory Specialist

Enclosures

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

### United States

Registrat Amendm Other	ion
Amendm	ent
Other	

OPP Identifier Number

<b>ŞEPA</b>	Environmental Protection Agency  Washington, DC 20460			х	Amendm Other	nent			
		Applicatio	n for Pesti	cide - Se	ection	ı I			<del></del>
1. Company/Product Numbe 7946-33	r		E .	PA Product M . Joyner	lanager			posed Classification  None Restric	
Company/Product (Name)     Mycoject Ultra Hp			PM#				X	None Restric	tea
5. Name and Address of App J.J. Mauget Co. 5435 Peck Road Arcadia, CA 91006 Check if Ihis is	olicant (Include ZIP Code a new address	e)	(b)(i to: EP	•	ct is sin		al in comp	FRA Section 3(c)(3) position and labeling	
			Section	- [[					
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Material This Product Wi									
Child-Resistant Packaging Yes No * Certification must	Unit Packaging Yes No If "Yes" Unit Packaging wgl.	No. Per Container	Water Soluble Yes No If "Yes" Package wgt	No. I	Per lainer		Jontainer Metal Plastic Glass Paper Other (Spec	cily)	
be submitted	driit i dexaging wgr.	Somemer	Touloge wat	]					
3. Location of Net Contents  Label C	Information Container	4. Size(s) Retail	Container		5. Loca	ation of Label D On label. On label accor		roduct.	
6. Manner in Which Label is	Affixed to Product	Lithogr Paper Stencil	glued	Other			·····		
			Section -	· IV				: : : :	
t. Contact Point (Complete	items directly below for	identification of	individua) lo be c	ontacted, if n	ecessar			· · · · · · · · · · · · · · · · · · ·	
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I certify that the statements I acknowledge that any knowledge that are the statements.		ing statement m	attachments the ay be punishable				€.	6. Data Application Rocelved (Stamped)	
2. Signature	ill_		3. Title Agent (SciRe	g, inc.)					
Typed Name     Frederick T. Smith		5	i. Date 1/31/0	2				. •	



FOR USE WITH LOADABLE TREE INJECTORS FOR SEASONAL SUPPRESSION OF CERTAIN DISEASES OF ORNAMENTAL TREES

MFG. BY:

TOWN, STATE:

EPA REGISTRATION NO:

EPA ESTABLISHMENT NO:

J.J. MAUGET CO. Arcadia, CA 9 t006 7946-33 7946-CA-t

ACTIVE INGREDIENT:

NOT REVIEWED

Oxytetracycline Hydrochloride in Accordance with PRivide 82-2. Long-sleeved shirt and long pants of the Riving Replients: OTHER INGREDIENTS: Based on Draft Labeling Dated

Net Contents:

t bottle @ 33.8 t fl. oz. (t liter)

4 bottles @ 33.8 t fl. oz. (t liter) ea.; t gal., 7.3 fl. oz. (4 liters) net

### KEEP OUT OF REACH OF CHILDREN **CAUTION**

	FIRST AID
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>Do not give anything to an unconscious person.</li> </ul>
IF ON SKIN	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for t5-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF IN EYES	<ul> <li>Hold eye open and rinse slowly and gently with waler for t5-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>

#### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact t-800-535-5053 for emergency treatment information.

#### NOTE TO PHYSICIAN

There is no specific antidote available. Treat patient symptomatically.

1/3 t/12

NOT REVIEWED
In Accordance with PR Notice 82-2 Based on Draft Labeling Dated

#### PRECAL FIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

Harmful if swallowed, Avoid contact with skin or clothing, Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco. or using the toilet. Wear long-sleeved and long pants, socks, shoes, and chemical-resistant gloves (such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Neoprene Rubber, Polyvinyl Chloride (PVC), Viton, Selection Category C). Avoid contact with eyes or clothing. Wear protective eyewear such as goggles, face shield or safety glasses. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

#### PERSONAL PROTECTIVE EQUIPMENT:

Some materials that are chemical-resistant to this product are listed below.

#### APPLICATORS AND OTHER HANDLERS MUST WEAR:

- Shoes plus socks
- · Chemical resistant gloves, such as polyethylene or butyl rubber or neoprene rubber or viton
- Protective eyewear such as goggles, face shield or safety glasses

#### **USER SAFETY REQUIREMENTS:**

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATIONS:

Users should:

- · Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

#### **ENVIRONMENTAL HAZARDS**

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

#### PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

Use within 6 months of the container-stamped packaged date.

#### NOTICE OF WARRANTY

To the extent consistent with applicable law, J.J. Mauget Co. makes no warranty of merchantability, fitness for any purpose or otherwise expressed or implied concerning this product or its uses which extends beyond the use of the project under normal conditions in accord with the statements made on this label.

#### DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO E THIS PRODUCT IN A MANNER INCONSIS. IT WITH ITS LABELING.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State or Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and the handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, wear:

- Coveralls over long-sleeved shirts and long pants
- · Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

#### APPLICATION EQUIPMENT

Mycoject Ultra Hp is a systemic antibiotic for use with liquid loadable injectors. Test Mycoject Ultra Hp compatibility with the injector and its liquid contact components before regular use. Clean the interior of the injector with a solvent cleaner to remove any residual liquid prior to use. Disinfect tree injector tips between each tree injection. Applicators must use liquid loadable injector equipment/devices with care and in a safe manner in addition to following each manufacturer's directions and precautions.

#### Micro-Injection Sites:

Measure the tree at chest height in inches. If measuring the circumference, divide this number by six (6) to determine the number of injection sites needed. If measuring the diameter, divide this number by 2 (two) to determine the number of injection sites needed. If the number of injection sites results in a fraction, round down to the lower whole number. Calculations result in 6 mL of product for every 6 inches of trunk circumference.

#### Drilling the Hole:

Depending on the specific type of applicator, it may be necessary to predrill holes prior to insertion of the applicator tip into the tree. Drill holes deep enough to allow the tree's vascular system to transport Mycoject Ultra Hp throughout the tree. Make injection holes at least ½ to ¾ inch into healthy xylem (white wood) with actual depth up to 2 inches or more from the outer trunk surface depending upon the tree species and outer bark thickness.

#### Application and Use:

Set the injector for the appropriate amount of Mycoject Ultra Hp per site and pressurize the injector. To account for trunk flare, place injection sites evenly spaced around the root buttress region avoiding root valleys. Follow good injection practices. Disinfect drill bit prior to use on each tree.

#### Uptake Time:

Uptake time in the tree usually occurs within several minutes to an hour dependant upon species of tree, soil moisture availability, and the type of tree injector.

Important: Do not use any part of treated trees or shrubs, including sap as food or feed. Preventative application is more effective than therapeutic treatment in trees showing disease symptoms. Trees in advanced stages of disease development may not respond to treatment. Infected trees will absorb the material more slowly due to the vascular plugging caused by the disease. If Mycoject Ultra Hp is not absorbed within 24 hours, the tree is considered high risk and has a poor chance of survival.

#### RESTRICTIONS

Do not inject trees that are less than two inches in diameter. This product is not to be used on trees that will produce food within the year following treatment.

#### APPLICATION, USE and DISEASE

Mycoject Ultra Hp is a ready-to-use antibiotic for use on non-crop bearing ornamental trees and large woody shrubs. Make applications when disease first appears. Mycoject Ultra Hp provides seasonal suppression of mycoplasmas, xylem-limited bacteria (Xylella fastidiosa, BLS), yellows oseases, and some bacterial blight diseases. Late summer or early fall applications provide disease suppression the following season. Some diseases may require repeated yearly application.

USE	DISEASE
Ash	Ash Yeliows
Elm	Bacterial Leaf Scorch, Phloem Necrosis
Gum (Sweet)/Liquidamber	Bacterial Leaf Scorch
Mountain ash (non-bearing)	Fire Blight
Oak	Bacterial Leaf Scorch
Palm	Paim Lethai Yeliows
Pear (non-bearing)	Fire Blight
Oleander	Bacterial Leaf Scorch
Sycamore	Bacterial Leaf Scorch

1/31/12

#### PESTICIDE STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE**: Store in a cool place over 45° F with units in an upright position. Do not expose material to temperatures in excess of 85°F for prolonged periods.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facilities.

**CONTAINER HANDLILNG:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose in a sanitary landfill, or by incineration. Do not burn unless allowed by state and local ordinances. Dispose of empty bottles in a sanitary landfill or by incineration if approved by state and local authorities. If burned, stay out of smoke.

1/31/12

## **NEW APPLICATIONS**

DATE: 6/6/11
FILE NUMBER: 7946-49
FEP (OPPIN ENTRY) pen 6/6/11
(Initial & date)
FILE ROOM:
(Initial & date)
SIG:
(Initial & date)
FILE ROOM:
(Initial & date)
X ASSIGN TO PM (NO DATA)
JACKET TO SHELF (DATA)

## Material Sent for Data Extraction

Reg. # 7996-66 / 1996-33
Description: New registration with label +CSF
☐ Material(s) Sent to Data Extraction Contractors:
New Stamped Label Dated
Notification Dated
New CSF(s) Dated 6 211
Other:
☐ Decision #:
Other Action/Comments:
File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the lacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.
Reviewer: Heathor GARVIE
Phone: $308034$ Division: $RD$
Date: 12/2/11



#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

7946-33

DEC 2 U 2011

Term of Issuance: Conditional

Name of Pesticide Product: Mycoject® Ultra Hp

Name and Address of Registrant (include ZIP Code):

J.J. Mauget Co. 5435 Peck Road Arcadia, CA 91006

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- 2. Revise the "EPA Registration Number to read, "EPA Reg. No. 7946-33.

Page	lof	2

Signature of Approving Official:

Date:

DEC 2 0 2011

Shaja B. Joyner, Product Manager (20)

Fungicide Branch, Registration Division (7505P)

EDA Form \$570-6

- 3. Update the Precautionary Statements to read, "Harmful if swallowed. Avoid contact with skin or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Neoprene Rubber, Polyvinyl Chloride (PVC), Viton, Selection Category C). Avoid contact with eyes or clothing. Wear (specify protective eyewear, if appropriate). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals."
- 4. Update the heading "Container Disposal" to "Container Handling" in the Storage and Disposal section on page 2.
- 5. Submit one copy of the revised final printed label for the record before the product is released for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Shaja B. Joyner

Product Manager (20)

Fungicide Branch

Registration Division (7505P)

Enclosures: Label stamped "Accepted with Comments"; TRB Acute Toxicology review (DP 392458)



SYSTEMIC ANTIBIOTIC
FOR USE WITH LOADABLE TREE INJECTORS FOR
SEASONAL SUPPRESSION OF CERTAIN
DISEASES OF ORNAMENTAL TREES

MFG. BY: TOWN, STATE: EPA REGISTRATION NO: EPA ESTABLISHMENT NO: J.J. MAUGET CO. Arcadia, CA 91006 7946-7946-CA-1 ACCEPTED with COMMENTS In EPA Letter Dates

In EPA Letter Dated

DEC 2 0 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

#### ACTIVE INGREDIENT:

#### Net Contents:

1 bottle @ 33.81 fl. oz. (1 liter) 4 bottles @ 33.81 fl. oz. (1 liter) ea.; 1 gal., 7.3 fl. oz. (4 liters) net

## CAUTION

	FIRST AID
IF SWALLOWED	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>Do not give anything to an unconscious person.</li> </ul>
IF ON SKIN	<ul> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
IF IN EYES	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> </ul>

6/3/11

Call a poison control cer r or doctor for treatment advice.

#### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-535-5053 for emergency treatment information.

#### NOTE TO PHYSICIAN

There is no specific antidote available. Treat patient symptomatically.

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

#### PERSONAL PROTECTIVE EQUIPMENT:

Some materials that are chemical-resistant to this product are listed below.

## APPLICATORS AND OTHER HANDLERS MUST WEAR:

- Long-sleeved shirt and long pants
- Shoes plus socks
- Chemical resistant gloves, such as polyethylene or butyl rubber or neoprene rubber or viton
- Protective eyewear such as goggles, face shield or safety glasses

#### **USER SAFETY REQUIREMENTS:**

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

## USER SAFETY RECOMMENDATIONS: Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.



#### **IVIRONMENTAL HAZARDS**

Do rick apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

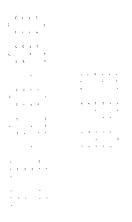
#### PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

Use within 6 months of the container-stamped packaged date.

#### NOTICE OF WARRANTY

To the extent consistent with applicable law, J.J. Mauget Co. makes no warranty of merchantability, fitness for any purpose or otherwise expressed or implied concerning this product or its uses which extends beyond the use of the product under normal conditions in accord with the statements made on this label.



#### **DIRECTIONS FOR USE**

IT IS A VIOLATION OF FEDERAL LAW . O USE THIS PRODUCT IN A LANKLR INCONSISTENT WITH ITS LABELING.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirement specific to your State or Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and the handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, wear:

- Coveralls over long-sleeved shirts and long pants
- · Chemical-resistant gloves made of any waterproof material
- Shoes plus socks

#### **APPLICATION EQUIPMENT**

Mycoject Ultra Hp is a systemic antibiotic for use with liquid loadable injectors. Test Mycoject Ultra Hp compatibility with the injector and its liquid contact components before regular use. Clean the interior of the injector with a solvent cleaner to remove any residual liquid prior to use. Disinfect tree injector tips between each tree injection. Applicators must use liquid loadable injector equipment/devices with care and in a safe manner in addition to following each manufacturer's directions and precautions.

#### Micro-Injection Sites:

Measure the tree at chest height in inches. If measuring the circumference, divide this number by six (6) to determine the number of injection sites needed. If measuring the diameter, divide this number by 2 (two) to determine the number of injection sites needed. If the number of injection sites results in a fraction, round down to the lower whole number. Calculations result in 6 mL of product for every 6 inches of trunk circumference.

#### Drilling the Hole:

Depending on the specific type of applicator, it may be necessary to predrill holes prior to insertion of the applicator tip into the tree. Drill holes deep enough to allow the tree's vascular system to transport Mycoject Ultra Hp throughout the tree. Make injection holes at least  $\frac{1}{2}$  to  $\frac{3}{4}$  inch into healthy xylem (white wood) with actual depth up to 2 inches or more from the outer trunk surface depending upon the tree species and outer bark thickness.

#### Application and Use:

Set the injector for the appropriate amount of Mycoject Ultra Hp per site and pressurize the injector. To account for trunk flare, place injection sites evenly spaced around the root buttress region avoiding root valleys. Follow good injection practices. Disinfect drill bit prior to use on each tree.

#### Uptake Time:

Uptake time in the tree usually occurs within several minutes to an hour dependant upon species of tree, soil moisture availability, and the type of tree injector.

Important: Do not use any part of treated trees or shrubs, including sap as food or feed. Preventative application is more effective than therapeutic treatment in trees showing disease symptoms. Trees in advanced stages of disease development may not respond to treatment. Infected trees will absorb the material more slowly due to the

vascular plugging caused by the "sear". If Mycoject Ultra Hp is not a norby within 24 hours, the tree is considered high risk and has a poor manual of survival.

#### RESTRICTIONS

Do not inject trees that are less than two inches in diameter. This product is not to be used on trees that will produce food within the year following treatment.

#### APPLICATION, USE and DISEASE

Mycoject Ultra Hp is a ready-to-use antibiotic for use on non-crop bearing ornamental trees and large woody shrubs. Make applications when disease first appears. Mycoject Ultra Hp provides seasonal suppression of mycoplasmas, xylem-limited bacteria (Xylella fastidiosa, BLS), yellows diseases, and some bacterial blight diseases. Late summer or early fall applications provide disease suppression the following season. Some diseases may require repeated yearly application.

<u>USE</u>	DISEASE
Ash	Ash Yellows
Elm	Bacterial Leaf Scorch, Phloem Necrosis
Gum (Sweet)/Liquidamber	Bacterial Leaf Scorch
Mountain ash (non-bearing)	Fire Blight
Oak	Bacterial Leaf Scorch
Palm	Palm Lethal Yellows
Pear (non-bearing)	Fire Blight
Oleander	Bacterial Leaf Scorch
Sycamore	Bacterial Leaf Scorch

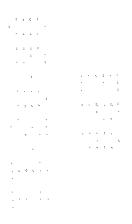
#### PESTICIDE STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in a cool place over 45° F with units in an upright position. Do not expose material to temperatures in excess of 85°F for prolonged periods.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facilities.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available, or puncture and dispose in a sanitary landfill, or by incineration. Do not burn unless allowed by state and local ordinances. **Dispose** of empty bottles in a sanitary landfill or by incineration if approved by state and local authorities. If burned, stay out of smoke.





#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

November 15, 2011

**MEMORANDUM:** Acute Toxicity DER for 7946-GG

Subject: Name of Pesticide Product: MYCOJET ULTRA HP

> EPA Reg. No. /File Symbol: 7946-GG DP Barcode: DP 392458 Decision No.: 450017 Action Code: R310

PC Code: 006308 (Oxytetracycline hydrochloride: 4.3%) Byer T. B. h.
NOJ. 15, 2011
Midadui
Lad ToxicologIST

From: Byron T. Backus, Ph.D., Toxicologist

> Technical Review Branch Registration Division (7505P)

To: Heather Garvie/Shaja Joyner RM 20

Fungicide Branch

Registration Division (7505P)

Registrant: J.J. MAUGET CO.

FORMULATION FROM LABEL:

Active Ingredient(s): by wt. 006308 Oxytetracycline Hydrochloride 4.3% Other Ingredient(s): 95.7% TOTAL 100.0%

#### **ACTION REQUESTED:** The Risk Manager requests:

"...Please review the attached acute inhalation study and dermal sensitization for this me-too product. The product (7269-GG) claims to be identical in formulation to EPA reg# 7946-32 with the only difference being the method of application. 7946-32 is applied via pre-loaded tree injectors fand 7946-GG is applied via liquid loadable tree injectors.

Included in this data package are the following: application letter from registrant; application form 8750-1; form 8570-27 (formulator's exemption); form 9570-34 (certification with respect to citation of data); a two page form used by the EPA screening contractors showing what data was submitted;

data matrix dated 6/8/11; hard copies of MRIDs 48498601 and 48498602; a draft product label; a draft CSF dated 6/2/11...

Also included in this package are the most recently accepted label for 7946-32 and the most recently accepted CSF for 7946-32..."

Action Requested: The Risk Manager requests a review of two (inhalation and dermal sensitization) acute toxicity studies (MRIDs 48498601-48498602).

GLP: The two studies were conducted in accordance with GLP.

Both of the acute toxicity studies have been classified as acceptable. These studies satisfy the acute inhalation toxicity (as Toxicity Category IV) and dermal sensitization (as a positive sensitizer) data requirements for the registration of EPA File Symbol 7946-GG (Mycoject Ultra Hp). In addition, the registrant is citing the following MRIDS: 47874204 (acute oral toxicity); 47874205 (acute dermal toxicity); 47874206 (primary eye irritation) and 47874207 (primary dermal irritation). These studies were previously reviewed by TRB (TXR 5011875; memorandum from Rick Whiting dated 12 March 2010 for 7946-GE) and classified as acceptable. The formulation is in EPA Toxicity Category III for oral toxicity (estimated LD<sub>50</sub>=3129 mg/kg), IV for dermal toxicity, III for primary eye irritation, and III for primary dermal irritation.

Deficiencies: There were no deficiencies.

Label Review:

PRODUCT ID #:

007946-00033

PRODUCT NAME:

MYCOJECT® ULTRA Hp

PRECAUTIONARY STATEMENTS

SIGNAL WORD: CAUTION

#### Hazards to Humans and Domestic Animals:

Harmful if swallowed. Avoid contact with skin or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Barrier Laminate, Butyl Rubber, Nitrile Rubber, Neoprene Rubber, Polyvinyl Chloride (PVC), Viton, Selection Category C). Avoid contact with eyes or clothing. [Wear protective eyewear.]\*

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

\*[protective eyewear may be specified, if appropriate].

#### First Aid:

#### If swallowed:

- -Call a poison control center or doctor immediately for treatment advice.
- -Have person sip a glass of water if able to swallow.
- -Do not induce vomiting unless told to by a poison control center or doctor.
- -Do not give anything to an unconscious person.

#### If on skin:

- -Take off contaminated clothing.
- -Rinse skin immediately with plenty of water for 15-20 minutes.
- -Call a poison control center or doctor for treatment advice.

#### If in eves:

- -Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- -Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- -Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician". The following statements are suggested types of information that may be included, if applicable: - technical information on symptomatology; - use of supportive treatments to maintain life functions; - medicine that will counteract the specific physiological effects of the pesticide; - company telephone number to specific medical personnel who can provide specialized medical advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

Additional note by reviewer: The study in MRID 48498602 demonstrates that this formulation is a positive dermal sensitizer. Based on the information received as part of the registration package for EPA File Symbol 7946-GG, EPA Reg. No. 7946-32 should be labeled as a dermal sensitizer.

The following table is the Acute Toxicity Data Evaluation Record for the two (acute inhalation and dermal sensitization) studies submitted for the proposed product, EPA File Symbol 7946-GG.

1. DP BARCODE: DP392458

2. PC CODE: 006308, Oxytetracycline hydrochloride 4.3%

3. CURRENT DATE: November 15, 2011

4. TEST MATERIAL: Mycoject Ultra Hp, containing 4.3% Oxytetracycline hydrochloride; a clear brown liquid; pH: 3.18

Study/Species/Lab Study # / Date	MRID	Results	Tox. Cat.	Core Grade
Acute inhalation toxicity/rat Eurofins PSL 30763 / January 5, 2011	48498601	$LC_{50}$ Males > 2.01 mg/L; $LC_{50}$ Females > 2.01 mg/L; $LC_{50}$ Combined > 2.01 mg/L. MMAD=2.57 $\mu$ m; GSD=2.32. All rats survived 4-hr exposure. Immediately following exposure 2M & 1F had irregular respiration and one of these males also had moist rales; an additional male was hypoactive at 1 hour after exposure. All rats were normal by day 4. 1M & 1F lost weight between day 0 and 7. There were no abnormalities at gross necropsy.	1V	A
Dermal sensitization/Guinea pig Eurofins PSL 30972 /Jan. 31, 2011	48498602	Buehler method. 0.4 mL Undiluted test material used for first and second induction; 0.4 mL 75% w/w mixture in distilled water for third induction. 0.4 mL 50% w/w mixture in distilled water used for challenge; 6/20 previously induced and 0/10 naïve controls had a positive response at challenge. Test material is considered to be a positive sensitizer.	Posi- tive	A

Core Grade Key: A = Acceptable, S = Supplementary, U = Unacceptable, W = Waived



RE: 7969-GG - CSF question Heather Garvie to: Fred Smith

08/02/2011 03:09 PM

Thank you!

Heather A. Garvie Registration Division Office of Chemical Safety and Pollution Prevention (7504P) 1200 Pennsylvania Ave. NW Washington, DC 20460 phone: 703-308-0034 www.epa.gov

Fred Smith

Heather-- Thanks for your email. I spoke with th... 08/02/2011 11:50:42 AM

From: To:

Fred Smith <fsmith@SciReg.com> Heather Garvie/DC/USEPA/US@EPA

Date:

08/02/20 t1 t1:50 AM

Subject:

RE: 7969-GG - CSF question

Heather --

Thanks for your email. I spoke with the registrant, J.J. Mauget, today and they confirmed that their establishment address on the CSF (5435 Peck Rd., Arcadia, CA 91006) is registered (Est. No. 7946-CA-1).

Kind regards,

--Fred

----Original Message----

From: Heather Garvie [mailto:Garvie.Heather@epamail.epa.gov]

Sent: Monday, August 01, 2011 2:06 PM

To: Fred Smith

Subject: 7969-GG - CSF question

Mr. Smith:

Regarding your pending application for EPA reg# 7946-GG (me too): Can you please let me know if the address in box 2 of your CSF is a registered establishment?

Thank you, Heather

\_\_\_\_\_\_

Heather A. Garvie Registration Division Office of Chemical Safety and Pollution Prevention (7504P) U.S.EPA 1200 Pennsylvania Ave. NW Washington, DC 20460 phone: 703-308-0034

## PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only) 3/23/09

21 Day Screen Start Date:	6 - 3-	//		
Experts In-Processing Signature:	MF	HARRING TON	Date 6-6-11	Fee Paid: Yes 🗸
Division management contacted or	issues	NoYe	sDate	

EPA Reg. Number: 7946-66 EPA Receipt Date: 6-3-1/								
	Items for I	Review			Yes	No	N/A*	
1	<b>Application Form</b> (EPA Form 8570-1 including package type	)(link to form) signed & co	mplete		$\times$			
2	Confidential Statement of Formula a dated (EPA Form 8570-4) (Link to form	-	igned, a	nd	$\lambda$			
	a) All inerts (link to http://www.epa.g including fragrances, approved f Footnote A)		yes \(	no	-			
3	Certification with Respect to Citation form) completed and signed (N/A if 10	•	)-34) (L	ink to	X			
	Certificate and data matrix consistent				X			
Quantitation of the state of th	If applicant is relying on data that are contours to pay statement included. (see Footnot)							
If applicable, is there a letter of Authorization for exclusive use only.  Formulator's Exemption Statement (EPA Form 8570-27) (Link to form)  completed and signed (N/A if source is unregistered or applicant owns the							Partition of the state of the s	
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)							
5	a) Selective Method (Fee category experts use)  yes no   X							
	b) Cite-All (Fee category experts use)							
	c) Applicant owns all data (Fee category experts use)							
5 Copies of Label (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> )  6 (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )								

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X	
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )		X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)		X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.  a) List study (or studies) not included with application		

Comments:

Studies passed 86-5 review.

6/7/11- Left a message on légistrants voicemail, regarding data not listed on data matrix.

6/8/11- Sp-he with registrant and sent an e-mail.

- Received a revised data matrix and an explanation e-mail explaining which data is required and which is not required.

Jacket passes

TJ 6/9/11

MRID 484986

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are strongly encouraged to verify that all inert ingredients have been approved for the application's uses even if a product is currently registered by consulting the inert Web

site [link to <a href="http://www.epa.gov/opprd001/inerts/lists.html">http://www.epa.gov/opprd001/inerts/lists.html</a>] and if the inert is not approved, to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at <a href="mailto:inertsbranch@epa.gov">inertsbranch@epa.gov</a> and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to

http://www.epa.gov/oppbppdl/biopesticides/contacts\_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <a href="http://www.epa.gov/opprd001/inerts/tips.pdf">http://www.epa.gov/opprd001/inerts/tips.pdf</a>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

- Correct the application by, for instance, correcting the inert's identity or CAS
  number, providing documentation that the inert has been approved, or
  removing the unapproved inert from the CSF or replacing it with one that is
  approved for the application's uses; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
- 3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

- 1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
- 2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

- B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.
- C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



### Data Matrix concerns (7946-GG)

Tracy Jackson to: fsmith

06/08/20 t1 03:48 PM

Hello Mr.Smith,

Per our telephone conversation regarding Mycoject Ultra Hp (7946-GG). Please verify if the data listed are required.

- 1. Preliminary Analysis 830.1700
- 2. Enforcement Analytical Method 830.1800
- 3. Explodability 830.6316
- 4. Miscibility 830.6319
- 5. Dielectric Breakdown Voltage 830.6321

If you have any questions I can be reached at 703-308-7227

Thank you

Tracy Jackson Macfadden/EPA Contractor 2777 S. Crystal Drive Arlington, VA 22202



RE: Data Matrix concerns (7946-GG)

Fred Smith to: Tracy Jackson

06/08/2011 04:12 PM

From:

Fred Smith <fsmith@SciReg.com> Tracy Jackson/DC/USEPA/US@EPA

To:

Hi, Tracy--

Relative to Mycoject Ultra Hp and the applicability of the following product chemistry guidelines, please see below.

- 1. Preliminary Analysis 830.1700: Not required. Active ingredient is not produced via integrated formulation process; active ingredient is supplied by EPA-registered source
- 2. Enforcement Analytical Method 830.1800: See attached revised data matrix (public and file copies).
- 3. Explodability 830.6316: Not Applicable. The product is not potentially explosive and does not contain potentially explosive components.
- 4. Miscibility 830.6319: Not Applicable. The product is not an emulsifiable liquid that will be diluted with petroleum solvents.
- 5. Dielectric Breakdown Voltage 830.6321: Not Applicable. Dielectric breakdown voltage testing is conditionally required if the end-use product is a liquid and is to be used around electrical equipment. The subject product will not be used around electrical equipment.

Please let me know if you have any further questions. Thanks very much.

#### Fred

Frederick T. Smith Senior Regulatory Specialist SciReg, Inc. 12733 Director's Loop Woodbridge, VA 22192 USA Phone: (703) 494-6500

Fax: (703) 492-6600 www.SciReg.com

----Original Message-----

From: Jackson.Tracy@epamail.epa.gov [mailto:Jackson.Tracy@epamail.epa.gov]

Sent: Wednesday, June 08, 2011 3:49 PM

To: Fred Smith

Subject: Data Matrix concerns (7946-GG)

Hello Mr. Smith,

Per our telephone conversation regarding Mycoject Ultra Hp (7946-GG). Please verify if the data listed are required.

- 1. Preliminary Analysis 830.1700
- 2. Enforcement Analytical Method 830.1800
- 3. Explodability 830.6316
- 4. Miscibility 830.6319
- 5. Dielectric Breakdown Voltage 830.6321

If you have any questions I can be reached at 703-308-7227

Tracy Jackson Macfadden/EPA Contractor 2777 S. Crystal Drive Arlington, VA 22202

# Script for Rejection Phone calls

First Call/Initials:  Date: 6/7/11  Time: 7:43 p. M.	Date:	l Call/Initials 6 letu 373 epon	<u>:</u>
This is	707	, EPA	contractor.
l'm calling regarding y Myloject			
We have found the foll PR Notice 86.5: Yes o Volume/Study T	r No	cies regardin	g:
Volume/Study T	itle:		
Volume/Study T	itle:		
Additional volum	nes continued	on back of pa	ige: Yes or No
Application Package:/	les or No		
Application Package: A data Missing f	som datom	atlix.	
These deficiencies have The corrections can be		*	a:
Second Call/Email: If we do not receive the your submission, accor	e corrections bedingly. Please	e direct all fu	ture calls and



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

June 6, 2011

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-450017

EPA File Symbol or Registration Number: 7946-GG

Product Name: MYCOJECT ULTRA HP

EPA Receipt Date: 03-Jun-2011 EPA Company Number: 7946

Company Name: J. J. MAUGET CO.

SCIREG, INC. J. J. MAUGET CO. 12733 DIRECTOR'S LOOP WOODBRIDGE, VA 22192-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

#### Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310
NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY);

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

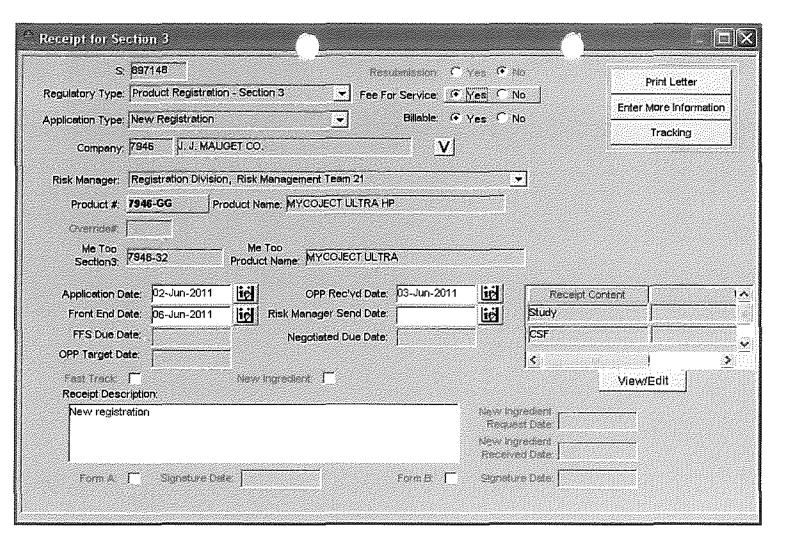
Front End Processing Staff

Information Technology & Resources Management Division

# Fee for Service

# {897148K~

This package includes the following	for Division		
<ul><li>New Registration</li><li>Amendment</li></ul>	○ AD ○ BPPD ● RD		
Studies?	Risk Mgr. 21		
Receipt No. S-	897148		
EPA File Symbol/Reg. No.	7946-GG		
Pin-Punch Date:	6/3/2011		
This item is NOT subject to	o FFS action.		
Action Code:	Parent/Child Decisions:		
Requested: คอเอ			
Granted: ଜ୍ଞାତ			
Amount Due: \$ 4807			
Inert Cleared for Intended Use	Uncleared Inert in Product		
Reviewer: 今·斯	Date: <u>@/@/n</u>		
Remarks:			



# SciReg, Inc. Science and Regulatory Consultants

June 3, 2011

U.S. Environmental Protection Agency Washington Finance Center FIFRA Service Fees P.O. Box 979074 St. Louis, MO 63197-9000

Re: PRIA Fee Payment

J.J. Mauget Co. (Co. No. 7946)

To Whom It May Concern:

On behalf of J.J. Mauget Co. (Co. No. 7946), enclosed please find a check for \$1,201.75 for Mauget's registration application for Mycoject Ultra Hp.

Should you have any questions, please let me know.

Sincerely,

Frederick T. Smith

Senior Regulatory Specialist

Enclosure

\*Commercial/financial information may be entitled to confidential treatment\*

J.J. MAUGET COMPANY	30150
5435 PECK ROAD ARCADIA, CA 91006-5847  DATE 5/11/11	90-3414/1222 10
PAY TO THE ORDER OF U.S. EPA  ORDER OF Housand two hundred one - 15/100 DOLLA	01.75
CITIZENS BUSINESS BANK	RS Li Delate on S
ILEO 30 1 50 III	MP N



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Oivision (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Oo not send the form to this address

	DATA	MATRIX				
Date 6/2/11			EPA Reg No./Fite Symbol 7946	A Reg No./Fite Symbol 7946-		
Applicant's/Registrant's Name & A	ddress		Product			
J.J. Mauget Company 5435 Peck Road Arcadia, CA 91006			Mycoject Ultra Hp			
Ingredient Oxytetracycline hyd	rochloride					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.1550	Product identity and composition	47874201	J.J. Mauget Co.	OWN		
830.1600	Description of materials used to produce the product	47874201	J.J. Mauget Co.	OWN		
830.1650	Description of formulation process	47874201	J.J. Mauget Co.	OWN		
830.1670	Discussion of the formation of impurities	47874201	J.J. Mauget Co.	OWN		
830.1750	Certified limits	47874201	J.J. Mauget Co.	OWN		
830,6302	Color	47874203	J.J. Mauget Co.	OWN		
830.6303	Pfrysical state	47874203	J.J. Mauget Co.	OWN		
830.6304	Odor	47874203	J.J. Mauget Co.	OWN		
830.6314	Oxidation/reduction	47874203	J.J. Mauget Co.	OWN		
830.6315	Flammability	47874203	J.J. Mauget Co.	OWN		
830.6317	Storage Stability	48309501	J.J. Mauget Co.	OWN		
830.6320	Corrosion Characteristics	48309501	J.J. Mauget Co.	OWN		
830.7000	рН	47874203	J.J. Mauget Co.	OWN		
830.7100	Viscosity	47874203	J.J. Mauget Co.	OWN		
830.7300	Density/relative density	47874203	J.J. Mauget Co.	OWN		
870.1100	Acute oral toxicity	47874204	J.J. Mauget Co.	OWN		
870.1200	Acute dermat toxicity	47874205	J.J. Mauget Co.	OWN		
870.1300	Acute inhalation toxicity	9 /9 # 19 # 20	J.J. Mauget Co.	OWN	Submitted herei	
870.2400	Primary eye irritation and an analysis and	47874206	J.J. Mauget Co.	OWN		
870.2500	Primary dermat irritation	47874207	J.J. Mauget Co.	OWN		
870.2600	Dermal sensitization		J.J. Mauget Co.	OWN	Submitted herei	
Signature July V	itl_		Name and Title Frederick T. Smith, Agent (SciReg,	Inc.)	Date 6/2/1130	



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden Jor this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for realting the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Oirector, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA	MATRIX			
Date 6/2/11		EPA Reg No./File Symbol 7	946-	Page 1 of 1	
Applicant's/Registrant's Name & Address			Product		
J.J. Matrget Company 5435 Peck Road Arcadia, CA 91006			Mycoject Ultra Hp		
ngredient Oxytetracycline hyd	rochloride				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Saatus	Note
			J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	OWN	
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	September 1		J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	NWO	
			J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	OWN	Submitted here
			J.J. Mauget Co.	OWN	
		l i	J.J. Mauget Co.	OWN	
			J.J. Mauget Co.	OWN	Submitted here
Signature			Name and Tirle Frederick T. Smitts, Agent (SciR	leg, Inc.)	Date 4/2/1/3

	A	
H-Mrm	Approved	

.ദ് No. 2070-0060. Approval expires 2-28-95

ΕΡΔ

#### United States

X	Registration
	Amendment
	Other

OPP Identifier Number

SEPA	Environment Wash	al Protection ington, DC 2046	_	у			Amend Other	ment	t			
		Application	n for Pe	sticide	e - Se	ction	n I					
t. Company/Product Number 7946- <i>GG</i>			2	EPA Pro M. Wal		ападег		]:	_	osed Class	·······•••	
4. Company/Product (Name) Мусојесt Ultra Hp			F	PM# 21					X	None	Restr	ricted
5. Name and Address of Applic J.J. Mauget Co. 5435 Peck Road Arcadia, CA 91006 Check if this is a		3)	(f) #1	b)(i), my o: EPA Re	produc eg. No.	et is sin	. In accorda nilar or ident 6-32 Dject Ultra					
-			Section	n - II								
Amendment - Explain be Resubmission in respons Notification - Explain bel  Explanation: Use additional	e to Agency letter date			Fin Age X "Me	ency let e Too" A	ed labels ter date Applicati	Юп.	to -				
Initial application for registra PRIA Category: R310 PRIA Fee: \$1,201.75 (after Conlact: fsmith@SciReg.co	75% fee reduction	)										
1. Material This Product Will	Po Pookagod to:		Sectio	<u>n - III</u>								
Child-Resistant Packaging Yes X No * Certification must be submitted	Unit Packaging  X Yes No  If "Yes" Unit Packaging wgt.	No. Per Container 4	Water Sol	es 0	No. F	<sup>2</sup> er ainer	2. Type o	Metal Plasti Glass Pape	ic S	'y)		
<u> </u>	ntainer	4. Size(s) Retai				5. <b>L</b> oca	ation of Label On label. On label acc			oduct.		
6. Manner in Which Label is A	lixed to Product	X Paper Stenci	glued		Other				.,			_
			Sectio									
Contact Point (Complete ite	ems directly below for	ı		e contact	ed, if ne	ecessarj	v, to process	·		<del></del>		
Frederick T. Smith			Title Telephone No. (Include 703/494-6500)		,	Area Code	e)					
I certify that the statements v I acknowledge that any know both under applicable law.		ng statement m	attachments	able by lin	e or imp			ete.		Recei	Application ved a <b>mned</b> )	
4. Typed Name  Frederick T. Smith			5. Date		···)					·		



June 3, 2011

Ms. Mary Waller
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Mycoject Ultra Hp

- Me-too Registration Application

Dear Ms. Waller:

On behalf of J.J. Mauget Co., SciReg, Inc. is submitting a me-too registration application for Mycoject Ultra Hp. This product is identical in formulation and use to Mycoject Ultra (EPA Reg. No. 7946-32), except that the proposed product will be applied via liquid loadable tree injectors, while Mycoject Ultra is applied via pre-loaded tree injectors.

This regulatory action falls under PRIA Category R300. Mauget requests a 75% small business PRIA fee reduction. Information supporting this request is attached.

If you have any questions regarding the application materials, please let me know.

Sincerely,

Frederick T. Smith

Senior Regulatory Specialist

Enclosures

#### TRANSMITTAL DOCUMENT

#### Submitter

J.J. Mauget Co. 5435 Peck Road Arcadia, CA 91006 SciReg, Inc. \*
12733 Director's Loop
Woodbridge, VA 22192

\* SciReg, Inc. is the authorized agent for J.J. Mauget Co.

Regulatory action in support of which this package is submitted

New Product Registration: Mycoject Ultra Hp

#### Transmittal Date

June 3, 2011

#### Contents

Volume 1 Administrative Materials

Volume 2 Acute Inhalation Toxicology Study in Rats (OPPTS 870.1300)

Volume 3 Dermal Sensitization Study in Guinea Pigs (OPPTS 870.2600)

Company Official: Frederick T. Smith Company Name: SciReg, Inc.

Company Contact: Frederick T. Smith (703) 494-6500

	E	PA
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United States

Environmental Protection Agency

WEITH	Washington, DC 20	3460	
₹ — - <b>*</b> "	Formulator's Exempti	on Statement	
	(40 CFR 152.		
Applicant's Name and Address		EPA File Symbol/Registration Nu	Imber
		7946 -	
J.J. Mauget Co.		Product Name	
5435 Peck Road		Mycoject Ultra Hp	
Arcadia, CA 91006		Date of Confidential Statement o	f Formula (EPA Form 8570-4)
		6/2/2011	
0 authorized representative of the	and the registration of the L		
As an authorized representative of the a	·	ofoduci identined above, i ci	ertify that; ; ;
(1) This product contains the followin	ig active ingredients(s):		
Oxytetracycline hydrochloride			
Oxytotracyoline nydrosinondo			
ingredient in the manufacturing, for which is registered under FIFRA seach use for which my product is  (3) Indicate by checking (A) or (B) be  (A) An accurate Confidential State attached to this statement. That for	Section 3, is purchased by us fro proposed to be labeled. Blow which paragraph applies: ement of Formula (EPA Form 88	om another producer, and is 570-4) for the above identific	s labeled for at least
name, the source of the active ing	gredient(s) listed in paragraph (1 <b>OR</b>	1).	·
(B) The Confidential Statement of complete, current, and accurate a	, , ,	· ·	on file with the EPA is
(4) The following active ingredients in	this product qualify for the forn	nulator's exemption.	
	Source		
Active Ingredient	Product Name	F	Registration Number
Oxytetracycline hydrochloride			
*Dussississississississississississis			1 1*
*Product ingredient source in	nformation may be enti	itled to confidential t	reatment
	1		
_			
Signature 4	Name and Title	Date ,	
SU1/Jull	Frederick T. Smith, AgenI (SciReg	1 . /	

EPA Form 8570-27 (Rev. 8-95)



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration

and 0.25 hours per response for reregistration and special review activities, including comments regarding burden estimate or any other aspect of this collection of informa		
Information Management Division (2137), U.S. Environmental Protection Agency, 40		
Do not send the completed form to this address.		
Certification with Respe	ct to Citation o	f Data
Applicant's/Registrant's Name, Address, and Telephone Number		EPA Registration Number/File Symbol
J.J. Mauget Co., 5435 Peck Road, Arcadia, CA 91006; 909/444-1057		7946-
Active Ingredient(s) and/or representative test compounds(s)		Date
Oxtetracycline hydrochloride		6/2/11
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)		Product Name
Terrestrial nonfood		Mycoject Ultra H <b>p</b>
NOTE: If your product is a t00% repackaging of another purchased EPA-registe submit this form. You must submit the Formulator's Exemption Statement (EPA Form	red product labeled fo 8570-27).	r all the same uses on your label, you do not need to
! am responding to a Data Call-In Notice, and have included with this form a list of complete used for this purpose).	anies sent offers of comp	pensation (the Data Matrix form should
SECTION I: METHOD OF DATA SU	IP <b>ORT</b> (Check on	e method only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).	under the sele	selective method ot support (or cite-all option ctive method), and have included with this form a of data requirements (the Data Matrix form must be
SECTION II: GENERA	L OFFER TO PA	Y
[Required if using the cite-all method or when using the cite-all option under the selec	tive method to satisfy	one or more data requirements[
I hereby offer and agree to pay compensation, to other persons, with regard to the appro-	val of this application, to	the <b>e</b> xtent required by £tFRA.
SECTION III: CE	RTIFICATION	
I certify that this application for registration, this form for reregistration, or this D application for registration, the form for reregistration, or the Data Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files tha substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application souguses.	addition, if the cite-all t (1) concern the prop is a type of data that the concern the property of the cite and the cite	option or cite-all option under the selective method is erties or effects of this product or an identical or would be required to be submitted under the data
I certify that for each exclusive use study cited in support of this registration or the written permission of the original data submitter to cite that study.	reregistration, that I are	n the original data submitter or that I have obtained
I certify that for each study cited in support of this registration or reregistration that submitter; (b) I have obtained the permission of the original data submitter to use the contensation have expired for the study; (d) the study is in the public literature; or (e) offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c) amount and terms of compensation, if any, to be paid for the use of the study.	study in support of this I have notified in writ	s application; (c) all periods of eligibility for ing the company that submitted the study and have
I certify that in all instances where an offer of compensation is required, copies accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	be submitted to the Ac	ency upon request. Should I fail to produce such
t certify that the statements t have made on this form and all attachments knowingly false or misleading statement may be punishable by fine or imprison		
Signature ### Alical	Date	Typed or Printed Name and Title
/ 11/16 et 1.1 477)	111.	Fraderick T Smith Agent (SciPeg Inc.)

### R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline	Group A: Product Chemistry Data	EP Data Submitted		MP Data Submitted		TGAI	
No.	Study Title	Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	X					
830.1650	Description of formulation process	Χ					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis not crewited		X				
830.1750	Certified limits (158.345)	Х					
830.1800	Enforcement analytical method	Ŷ.		i			

Guideline			EP Data Submitted		MP Data Submitted		,
No.			No	Yes	No	Y <b>e</b> s	No
830.6302	Color	X					
830.6303	Physical State	Χ					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	Х		-			
830.6315	Flammability	X		<u>.</u>			
830.6316	Explodability 1/A		义				
830.6317	Storage stability	X					
830.6319	Miscibility N/A	<u> </u>	X			<u></u>	
830.6320	Corrosion Characteristics	Χ					
830.6321	Dielectric Breakdown Voltage N/A		X				
830.7000	pH	X					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	X					
830.7200	Melting Point						
830.7220	Boiling Point	E .					
830.7300	Density	X					ļ
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

### R 310

à

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline	Acute toxicity (6 pack)	Data submitted		Cited	
No.	Study Title	Yes	No	Yes	No
870.1100	Acute Oral (LD50)	X			
870.1200	Acute Dermal (LD50)				
870.1300	Acute Inhalation (LC50)	<u> </u>			
870.2400	Acute Eye Irritation	X			
870.2500	Acute Dermal Irritation	1			
870.2600	Dermal Sensitization	X			

Efficacy – which guideline is used depends on the proposed label use

Guideline	not lequille	Data submitted Cite		ed		
No.	Study Title	Yes	No	Yes	No	Comments
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					**************************************
810.3800	Methods for Efficacy Testing of Termite Baits					

Form Approved OMB No. 2070-0050



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send the form to this address	DATA	VIATRIX			— namentaria — naminibani
Date 6811			EPA Reg No /Ete Syndrol 7948	v	Page 1 of 1
Applicarif's/Registrant's Name & A	ddress		Frantuc;		
J.J. Mauget Comp∌ny 5435 Peck Road Arcadia, CA 91006			Mycoject Ultra Hp		
ingredient. Oxytetracydline hyd.	rodillonde				
Guideline Reference Number	Gutkine Sindy Name	MRID Number	Sidninger	Status	Note
830,1550	Product identity and composition	47874201	J.J. Mauget Co.	OWN	
830.1600	Description of materials used to produce the product	47874201	J.L. Mauget Co.	OWN	
830.1650	Description of formulation process	47874201	J.J. Mauget Co.	OWN	
830.1670	Discussion of the formation of imporities	47874201	J.J. Mauger Co.	OWN	
830.1750	Certified limits	47674201	J.J. Marget Co.	OWN	
830,1800	Analytical method	48022201	J.J. Mauget Co.	OWN	
830_6302	Cotor	47874203	J.J. Mauget Co.	OWN	
830.6303	Physical state	47874203	J.J. Mauget Co.	NWO	
830,6304	Ottor	47874203	J.J. Mauget Co.	OWN	
830,6314	Oxidation/reduction	47874203	J.J. Mauget Co.	OWN	
830.6315	Flammability	47874203	J.J. Mauget Co.	OWN	
830,6317	Storage Stability	48309501	J.J. Manget Co.	OWN	
830,6320	Corrosion Characteristics	48309501	J.J. Mauget Co.	OWN	
830,7000	ρ <del>1</del> 3	47874203	J.J. Mauget Co.	OWN	
830.7100	Viscosity	47874203	J.J. Matiget Co.	OWN	
830,7300	Density/relative density	47874203	J.J. Mauget Co.	OWN	
870.1100	Acute oral toxicity	47874204	J.J. Mauget Co.	OWN	
870.1200	Acide dermat loxicity	47874205	J.J. Mauget Co	OWN	
870,1300	Acute inhalation toxicity		J.J. Mauget Co.	OWN	Suhmitted hereir
870,2400	Primary eye irmation	47874206	d.J. Mauget Co.	OWN	
870,2500	Primary dermal irritation	47874207	J.J. Mauget Co.	OWN	
870,2600	Dermal seosdization		J.J. Manget Co.	OWN	Submitted hereic
Signature	:- C		Name and Title Frederick T. Smith, Agent (SciReg.	Inc.)	6/8/11

Form Approved OMB No. 2070-0060



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		DATA	MATRIX			
Date 6/8/11				EPA Reg No./File Symbol	7946-	Page 1 of
Applicant's/Registrant's Name & A	ddress			Product		
J.J. Mauget Company 5435 Peck Road Arcadja, CA 91006				Mycoject Ultra Hp		
ingredient Oxytetracycline hyd	rochloride					
Guideline Reference Number	Guideline Study Name		MRIO Number	Submitter	Status	Note
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
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				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	-
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	Submitted here
				J.J. Mauget Co.	OWN	
				J.J. Mauget Co.	OWN	
					OWN	Submitted here
Signature 4	• 0			Name and Title		Date
au / N	JT			Frederick T. Smith, Agent	(SciReg, Inc.)	6/8/11

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